

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Maria Cristina Rosa Geroni, et al.	Examiner:	Unassigned
Serial No:	10/549,713	Art Unit:	Unassigned
Filed:	September 16, 2005	Docket:	18269 (PC27483A)
For:	COMBINED THERAPY AGAINST TUMORS COMPRISING NEMORUBICIN WITH RADIATION THERAPY	Dated:	October 26, 2005

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT


In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. United States Patent No. 4,672,057, dated June 9, 1987 to Bargiotti et al.;
2. United States Patent No. 4,710,564, dated December 1, 1987 to Otake et al.;
3. Bonner J.A. et al., "Doxorubicin Decreases the Repair of Radiation-Induced DNA Damage", *International Journal of Radiation Biology*, 57(1):55-64 (1990), XP-009033771;

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Dated: October 26, 2005


Peter I. Bernstein

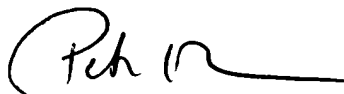
4. Kabuto M. et al., "Antitumor Effect of MX2, a New Morpholino Anthracycline Against C6 Glioma Cells and its Combination Effect with Photodynamic Therapy in Vitro!", *Brain and Nerve*, 47(10):969-973 (1995), XP-009033767;
5. UK Patent Publication No. GB 2 294 495 A, published May 1, 1996;
6. UK Patent Publication No. GB 2 296 495 A, published July 3, 1996;
7. UK Patent Publication No. GB 2 315 067 A, published January 21, 1998;
8. UK Patent Publication No. GB 2 325 067 A, published November 11, 1998;
9. Bonner J.A. et al., "Doxorubicin Enhances Radiation-Induced DNA Damage", *International Journal of Radiation Oncology, Biology, Physics*, 15(1):163 (1988), XP-009033770;
10. Chenoufi N. et al., "In Vitro Demonstration of Synergy Between Radionuclide and Chemotherapy", *The Journal of Nuclear Medicine*, 39(5):900-903 (1998), XP-009033769;
11. Wu Li-Teh, "Doxorubicin as Radiation Potentiator: Concurrent Doxorubicin and Radiation Therapy Interaction and its Clinical Application", *Infusion Chemotherapy-Irradiation Interactions, Chapter 13*:147-151 (1998), XP-002289046;
12. Jagetia G.C. et al., "Effect of Doxorubicin on Cell Survival and Micronuclei Formation in HeLa Cells Exposed to Different Doses of Gamma-Radiation", *Strahlentherapie Onkologie*, 176(9):422-428 (2000), XP-002289047;
13. Beulz-Riche D. et al., "Metabolism of Methoxymorpholino-Doxorubicin in Rat, Dog and Monkey Liver Microsomes: Comparison with Human Microsomes", *Fundamental & Clinical Pharmacology* 15:373-378 (2001);
14. Fraier D. et al., "LC-MS-MS Determination of Nemorubicin (Methoxymorpholinyl-doxorubicin, PNU-152243A) and its 13-OH Metabolite (PNU-155051A) in Human Plasma", *Journal of Pharmaceutical and Biomedical Analysis* 30(3):377-389 (2002);
15. Geroni C. et al., "The Combination of Nemorubicin with Cisplatin and Mitomycin C is Synergistic in Experimental Tumor Models", *European Journal of Cancer*, page S20 (2002), XP-004403486;

16. Geroni C. et al., "Preclinical Activity Against Liver Metastases of Nemorubicin, a DNA-Intercalating Cytotoxic Agent for the Treatment of Hepatocellular Carcinoma", *European Journal of Cancer* 38:S19 (2002), XP-004403483;
17. Opolski A. et al., "Properties of the New Anthracycline Derivative Containing Modified Daunosamine Moiety", *European Journal of Cancer* 38:S19-S20 (2002), XP-004403485; and
18. PCT International Publication No. WO 03/082267 A1, published October 9, 2003.

Reference nos. 1-4, 6, 7, 9-12 and 15-18 were cited in a Search Report dated August 5, 2004 received from the European Patent Office. Applicants are submitting copies of the above-cited references, together with a copy of the Search Report. The relevance of above-identified reference nos. 11-4, 6, 7, 9-12 and 15-18 has been described in the Search Report. The relevance of above-identified reference nos. 1, 2, 8, 13 and 14 has been described in the specification.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. §1.97(b), no statement or fee is required.

Respectfully submitted,



Peter I. Bernstein
Registration No.: 43,497

Scully, Scott, Murphy & Presser
400 Garden City Plaza, Suite 300
Garden City, New York 11530
(516) 742-4343

PIB:dg

Form PTO-1449 (REV. 7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE <div style="text-align: center;">LIST OF PRIOR ART CITED BY APPLICANT</div> <p style="text-align: center;"><i>(Use several sheets if necessary)</i></p>		Atty. Docket No. (Optional) 18269 (PC27483A)	Application Number 10/549,713				
		Applicant(s) Maria Cristina Rosa Geroni, et al.					
		Filing Date September 16, 2005	Group Art Unit Unassigned				
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL*		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA	4,672,057	6/9/87	Bargiotti et al.			
	AB	4,710,564	12/1/87	Otake et al.			
FOREIGN PATENT DOCUMENTS							
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
		GB 2 294 495 A	5/1/96	United Kingdom			
		GB 2 296 495 A	7/3/96	United Kingdom			
		GB 2 315 067 A	1/21/98	United Kingdom			
		GB 2 325 067 A	11/11/98	United Kingdom			
		WO 03/082267 A1	10/9/03	PCT			
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
		Bonner J.A. et al., "Doxorubicin Decreases the Repair of Radiation-Induced DNA Damage", <i>International Journal of Radiation Biology</i> , 57(1):55-64 (1990), XP-009033771					
		Kabuto M. et al., "Antitumor Effect of MX2, a New Morpholino Anthracycline Against C6 Glioma Cells and its Combination Effect with Photodynamic Therapy in Vitro!", <i>Brain and Nerve</i> , 47(10):969-973 (1995), XP-009033767					
		Bonner J.A. et al., "Doxorubicin Enhances Radiation-Induced DNA Damage", <i>International Journal of Radiation Oncology, Biology, Physics</i> , 15(1):163 (1988), XP-009033770					
		Chenoufi N. et al., "In Vitro Demonstration of Synergy Between Radionuclide and Chemotherapy", <i>The Journal of Nuclear Medicine</i> , 39(5):900-903 (1998), XP-009033769					
EXAMINER			DATE CONSIDERED				
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO-1449 (REV. 7-80) PATENT AND TRADEMARK OFFICE LIST OF PRIOR ART CITED BY APPLICANT <i>(Use several sheets if necessary)</i>		Atty. Docket No. (Optional) 18269 (PC27483A)		Application Number 10/549,713				
		Applicant(s) Maria Cristina Rosa Geroni, et al.						
		Filing Date September 16, 2005		Group Art Unit Unassigned				
FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>								
		Wu Li-Teh, "Doxorubicin as Radiation Potentiator: Concurrent Doxorubicin and Radiation Therapy Interaction and its Clinical Application", <i>Infusion Chemotherapy-Irradiation Interactions, Chapter 13</i> :147-151 (1998), XP-002289046						
		Jagetia G.C. et al., "Effect of Doxorubicin on Cell Survival and Micronuclei Formation in HeLa Cells Exposed to Different Doses of Gamma-Radiation", <i>Strahlentherapie Onkologie</i> , 176(9):422-428 (2000), XP-002289047						
		Beulz-Riche D. et al., "Metabolism of Methoxymorpholino-Doxorubicin in Rat, Dog and Monkey Liver Microsomes: Comparison with Human Microsomes", <i>Fundamental & Clinical Pharmacology</i> 15:373-378 (2001)						
		Fraier D. et al., "LC-MS-MS Determination of Nemorubicin (Methoxymorpholinyl)doxorubicin, PNU-152243A) and its 13-OH Metabolite (PNU-155051A) in Human Plasma", <i>Journal of Pharmaceutical and Biomedical Analysis</i> 30(3):377-389 (2002)						
		Geroni C. et al., "The Combination of Nemorubicin with Cisplatin and Mitomycin C is Synergistic in Experimental Tumor Models", <i>European Journal of Cancer</i> , page S20 (2002), XP-004403486						
		Geroni C. et al., "Preclinical Activity Against Liver Metastases of Nemorubicin, a DNA-Intercalating Cytotoxic Agent for the Treatment of Hepatocellular Carcinoma", <i>European Journal of Cancer</i> 38:S19 (2002), XP-004403483						
		Opolski A. et al., "Properties of the New Anthracycline Derivative Containing Modified Daunosamine Moiety", <i>European Journal of Cancer</i> 38:S19-S20 (2002), XP-004403485						
EXAMINER			DATE CONSIDERED					
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

PCT

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c))					Docket No. 18269 (PC27483A)	
In/Re Application Of: Maria Cristina Rosa Geroni, et al.						
Application No. 10/549,713		Filing Date September 16, 2005	Examiner Unassigned	Customer No. 23389	Group Art Unit Unassigned	Confirmation No. Unassigned
Title: COMBINED THERAPY AGAINST TUMORS COMPRISING NEMORUBICIN WITH RADIATION THERAPY						
<p>Address to:</p> <p>Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450</p> <p>37 CFR 1.97(b)</p> <p>1. <input checked="" type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.</p> <p style="text-align: center;">37 CFR 1.97(c)</p> <p>2. <input type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:</p> <p style="margin-left: 40px;"><input type="checkbox"/> the statement specified in 37 CFR 1.97(e);</p> <p style="text-align: center; margin: 10px 0;">OR</p> <p style="margin-left: 40px;"><input type="checkbox"/> the fee set forth in 37 CFR 1.17(p).</p>						

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
18269 (PC27483A)

In Re Application of: **Maria Cristina Rosa Geroni, et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/549,713	September 16, 2005	Unassigned	23389	Unassigned	Unassigned

Title: **COMBINED THERAPY AGAINST TUMORS COMPRISING NEMORUBICIN WITH RADIATION THERAPY**

Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of _____ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **19-1013/SSMP** as described below.
- ☐ Charge the amount of _____
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

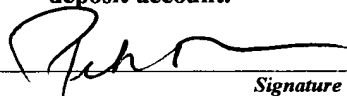
Certificate of Transmission by Facsimile*

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. _____) on _____ (Date)	
_____ Signature	
_____ Typed or Printed Name of Person Signing Certificate	

Certificate of Mailing by First Class Mail

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>October 26, 2005</u> (Date)	
_____ Signature of Person Mailing Correspondence	
Peter I. Bernstein	
_____ Typed or Printed Name of Person Mailing Certificate	

***This certificate may only be used if paying by deposit account.**


Signature

Dated: **October 26, 2005**

Peter I. Bernstein
Registration No. 43,497

CC: